

## **REMARKS**

Claims 11-16, 51, and 57-75 will be in the application after entering the above amendments. Claims 17-50 and 52-56 have been cancelled. New Claims 63-75 have been added.

Claims 11 and 51 have been amended to define the removal of native oxide as being done (i) with minimum consumption of the metal (see US 5,876,453, column 5, lines 16-20) and (ii) without contacting the metal surface with non-titanium particles (see US 5,876,453, column 5, line 62 to column 6, line 2). These statements are included in a passage introduced in an amendment mailed March 11, 1999 to include portions of the specification of US 5,876,453, which is incorporated by reference and is commonly owned. These statements further distinguish claims 11 and 51 from the principal references, Haruyuki and Schulte.

Claims 63-75 have been added to describe in more detail implants according to the invention. The added features within these claims include:

- a smooth head portion
- a cylindrical section within the threaded portion
- a tapered section within the threaded portion and adjacent to the lowermost end
- a self-tapping region
- a threaded portion with continuous thread turns
- an acid-etched surface on the threaded portion section and extending to the lowermost end of the implant

Support for these features may be found in the implant shown in Figure 1 and the corresponding portion of the specification.

### **I. Rejections Under 35 U.S.C. § 112**

Claims 11-25, 27-32, 35-49, and 51-59 have been rejected under 35 U.S.C. 112 first paragraph as not conveying to one skilled in the art that the inventor had possession of the claimed invention. More specifically, the Examiner objects to the use of the word "substantially" in connection with the amount of native oxide removed and with the array of irregularities on the etched metal surface. The Examiner contends that one skilled in the art would not be able to determine what degree of roughness or amount of native oxide removed would be within the

scope of the claims. However, as the photomicrographs make clear, the word “substantially” is appropriate. The claims are as precise as the subject matter permits. See *Andrew Corporation vs. Gabriel Electronics Inc.*, 6 U.S. P. Q. 2d, 2010 (1988).

Deleting the word would not improve certainty. When the word is deleted, the claims would still need to be construed in accordance with the specification, which makes it clear that there is no such thing as a **perfectly** “uniform array of irregularities” when the surface is acid etched. For example, it is impossible to have each irregularity within the array be a perfectly and identically shaped cone. The specification also makes it clear that it is possible that some minimal patches of native oxide may remain on the threaded surface. Consequently, even when the “substantially” term is deleted and the skilled artisan reads the claims in light of the specification, it is clear that he or she would appreciate that each irregularity in the array of irregularities cannot be identical, nor could each particle of native oxide be assured of removal.

The Examiner is urged to reconsider his rejection or to suggest alternative language that he believes would obviate the rejection.

## **II. Rejections Based on Haruyuki, Krueger, and Niznick**

Claims 11-16, 22-25, 27-33, 35-49, and 54-59 have been rejected under 35 U.S.C. 103(a) as being obvious over Haruyuki et al (“Haruyuki”) in view of Krueger. Haruyuki was cited for a titanium implant surface with recesses having depths of 0.5 to 5 microns. Krueger was cited for the location of a roughened surface on a threaded dental implant.

Krueger previously had been employed by the Examiner as a principal reference, not merely for his use of threads on a dental implant. In the previous correspondence on this application, Applicants have consistently stated that Krueger is not useful for rejecting these claims because Krueger’s disclosure is not enabling. Regarding the present rejection, Applicants respectfully suggest that Krueger cannot be combined with Haruyuki to arrive at the invention of claims 11-16 and 57-59 for several reasons.

As the Examiner is aware, the **entire** teaching of the reference must be considered, including the portions that teach away from the invention. Krueger states that the entire surface of the implant should be “etched so as to increase its effective or actual surface area **to as great an extent as reasonably possible.**” Column 3, lines 50-53 (emphasis added). Here, Krueger is referring to surface 12, which can be seen in Figure 3 to cover both the head portion and the

thread portion of the implant. In other words, the entire surface of Krueger's implant from the uppermost surface to the lowermost surface is roughened **"to as great an extent as reasonably possible."**

This is clearly contrary to the teachings of Haruyuki. Haruyuki uses a post-treatment of HF and H<sub>2</sub>O<sub>2</sub> to smoothen the surface created by the pre-treatment and describes processes that should be avoided because they do not smoothen the surface. (Translation, page 4, left column). Because Haruyuki teaches smoothing the sharp edges produced by the pre-treatment, it is impermissible to combine Krueger with Haruyuki since Krueger teaches away from Haruyuki. See MPEP § 2145(X)(2).

Additionally, many of the claims (e.g. amended independent claim 51) require a smooth head portion. Because Krueger specifically teaches that the roughened portion should extend to the uppermost surface, Krueger specifically teaches away from the claimed inventions that require a smooth head portion. This is yet another reason as to why Krieger cannot be used to reject claims requiring a smooth head portion.

Regarding claims 12 and 57-59, Krueger fails to suggest any concern with the native oxide that the Applicant removes before roughening the titanium surface. Consequently, Krueger is only pertinent for his teaching on where to locate a roughened surface on the threaded implants. Even so, the Examiner still states that he considers that the surface irregularities of Krueger would inherently be the same as set forth in the claims. Office Action, pages 4-5. In view of the deficiencies of Krueger, who provides no visual evidence of his titanium surface, the Applicants contend the Examiner's position is unsupported and should be withdrawn.

Haruyuki teaches a two step process by which he creates a rough surface on titanium implants. In contrast to the process of the Applicants, Haruyuki produces a rough surface on titanium with his pre-treatment with a solution of hydrofluoric acid. This is clear from the photographs reproduced in Exhibit I of the Gubbi declaration. See Figure 2. When compared with the surface produced by the Applicants' process, in which a minimum amount of titanium metal is removed after the native oxide has been consumed (see Exhibit A, Stage 1), it is evident that the titanium surface is relatively smooth and not roughened. In the Applicants' process, roughening occurs only in the second step in which the oxide-free surface is roughened by an acid treatment. Therefore, as amended, the claims could no longer be considered to be obvious.

The Examiner argues that he need not give weight to the process steps, but the result of the first step of Haruyuki is clearly different from that of the Applicants. The reason for the difference is not evident from the Haruyuki translation, but the difference is.

Claims 17-21 and 51-53 were rejected under 35 U.S.C. 103(a) as unpatentable over Haruyuki and Krueger and further in view of Niznick, who was cited for the use of different regions of roughness in dental implants. Only claims 51-53 are still pending. The proposed combination fails to render obvious claims 51-53 for at least three reasons.

First, Haruyuki and Krueger cannot be combined for the reasons mentioned above, and the proposed combination of claims 51-53 fails for this reason alone. Second, Niznick is not useful for rejecting claims 51-53 because, in stark contrast to the Applicants' uniform roughness having a peak-to-valley height of not greater about 10 microns, Niznick teaches the use (i) of **at least a 25 micron roughness** at the middle of his implants and (ii) a head portion 5 and the bottom threaded region 8 having peak-to-valley heights of up to 20 microns. See Niznick's claim 1. Claim 51 requires (i) a smooth upper surface and (ii) that the roughened region (i.e., a substantially uniform array of irregularities) in the threaded portion extends to the lowermost surface of the implant. As such, Niznick clearly teaches away from the invention of claims 51-53. And third, considering that Krueger teaches to roughen the **entire** surface of the implant from the uppermost surface to the lowermost surface **to as great an extent as reasonably possible**, Niznick selective placement of certain surfaces teaches away from any proposed combination with Krueger. See MPEP § 2145(X)(2).

Applicants respectfully suggest that claims 51-53 are patentable over the proposed combination of Haruyuki, Krueger, and Niznick.

### **III. Rejection Based on Schulte**

Claims 11-16, 22, 24, 25, 27-33(32?), 36-39, and 54-56 were rejected under 35 U.S.C. 102(b) as anticipated by Schulte et al (Schulte), or alternatively under 35 U.S.C. 103(a). Only claims 11-16 remain pending. The rejection under 35 U.S.C. 102(b) should be withdrawn, since Schulte could not anticipate claims 11-16. Schulte does not enable one skilled in the art to practice the Applicant's invention because it very briefly mentions that the surface was grit-blasted and acid-etched.

To prove that Schulte was not enabling, Applicants went to great lengths to test a matrix of acids after the titanium implant was grit blasted. Applicants consulted with the Examiner prior to this substantial testing so that the Examiner would understand the substantial testing that Applicants were intending to perform to determine whether that the skilled artisan could arrive at Schulte's surface based on Schulte's minimal teaching of the process. See Examiner's Interview dated November 20, 2002. The concept was simple. If any of the tests showed a surface similar to Schulte's, then it was enabling. If they did not, then Schulte could not be considered enabling considering the substantial tests that Applicants performed. **The tests showed no surface even remotely similar to that which is disclosed in Schulte or the Applicants' inventive surface.** See Declaration of Dr. Gubbi, and Reply dated July 23, 2003. Hence, the tests prove that Schulte is non-enabling and cannot be used to reject these claims.

Yet, the Office Action states "the Examiner posits that Schulte is sufficiently clear such that one can make a determination as to what is disclosed thereby. In particular, the claims of the present application are broadly recited with 'substantially' and product-by process format such that they are read on by what is disclosed by Schulte." Office Action, page 8. The Applicants respectfully suggest that Examiner's position is inconsistent with the U.S. patent laws. Even if a reference discloses all of the elements of a claim, it cannot anticipate that claim if it does not enable the skilled artisan how to make the allegedly anticipatory structure. See *In re Paulsen*, 30 F.3d 1475 (Fed. Cir. 1994); *Rockwell International Corp. v. United States*, 147 F.3d 1358 (Fed. Cir. 1998). To be enabling, the prior art reference must teach the skilled artisan how to make the invention without undue experimentation. *In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993).

Here, Applicants have proven that the surface disclosed in Schulte cannot be replicated by various processes that were tested. That being the case, Schulte cannot be used to reject the claims because it is not enabling with respect to the surface it discloses. The enablement issue is not (as the Examiner suggests) -- can the skilled artisan understand what the surface discloses? Rather, the enablement issue is - - could the skilled artisan make Schulte's surface with the information provided in Schulte. The answer is "NO." Keep in mind that the Applicants have already provided the Examiner with several items attributed to Schulte and Friatec and none of them discloses the process by which this surface is made. See the amendment dated April 22, 2002. It appears that Schulte and Friatec consider this process a trade secret and have

purposefully withheld the details as to how to make the surface. Holding the details of a process as a trade secret is, of course, the antithesis of an enabling disclosure. For this reason, Applicants again request that the Examiner withdraw the rejection based on Schulte.

Regarding the substance of Schulte, Schulte was cited for irregularities 2 to 5 microns high and, particularly, for Figure 14 and its caption. Claim 11 now requires that the implant have its native oxide layer removed without contacting the surface with non-titanium particles, which can cause contamination. See US 5,876,453, column 5, line 62 to column 6, line 2. Schulte's Figure 13 states that a screw-type implant was blasted with aluminum oxide powder, which appears to have created a very rough surface and can leave aluminum oxide particles on the titanium surface.

#### **IV. New Claims 63-75**

New claims 63-75 distinguish over the prior art references in several ways. First, unlike Niznick, these claims require the acid-etched surface to extend to the lowermost end, and the roughened surface of Niznick is substantially different from Applicants' surface. Claims 63 and 75 require a smooth machined surface on the head portion, which is also much different from Niznick and Krueger. Claims 63 and 68 require a threaded portion with continuous thread turns, which is much different from the individual and distinct thread sections on the Frialit 2's stepped implant body, as touted by Schulte. Claim 63 also requires native oxide to be removed without non-titanium particles, which is the antithesis of Schulte's aluminum oxide. Claim 68 also requires the threaded portion to include a cylindrical section and a tapered section at the lowermost end, which is also much different from the individual and distinct thread sections on the Frialit 2's stepped implant body, as touted by Schulte. Again, Schulte teaches the benefits of the Frialit-2 system, which has a tapered, stepped shape with threads only on the steps and not on the entire implant. See page 8, right column. Thus, the Frialit-2 implants differ from the Applicants in their structure as well as their surface. Claims 65-67 and 7-72 deal with process steps that are also not taught in the prior art.

#### **V. Product by Process Claims**


*The Examiner* relies on MPEP § 2113 for the proposition that it is the resulting surface that is being claimed and not the process. While it is true that the claims are directed to the resulting surface, it does not follow that the process can be ignored when evaluating the claims. It is acceptable to describe a surface by the process used to create it if that process adequately describes a surface that is distinguishable from the prior art. From the prior art references and the tests conducted by Dr. Gubbi, it can be seen that different processes may create different surfaces. Hence, the Applicants respectfully request that the Examiner not ignore the process steps required by the pending claims.

#### **VI. Conclusion**

If the Examiner considers that further amendment is needed, he is invited to contact the Applicant's attorney at the telephone number provided below.

The Commissioner is hereby authorized to charge deposit Account No. 10-0447 (47168-00035USC1) for any fees inadvertently omitted which may be necessary now or during the pendency of this application, except for the issue fee.

Respectfully submitted,



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